



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

July 20, 2000

VIA HAND DELIVERY

In reply refer to Warning Letter SEA 00-61

John M. Sterk, Owner
Jonal Dairy
6432 Chasteen Road
Lynden, Washington 98264

WARNING LETTER

Dear Mr. Sterk:

An investigation at your dairy located at 6432 Chasteen Road, Lynden, Washington, by our investigator on June 1, 2000, confirmed that you offered an animal for sale for slaughter as food in violation of Section 402(a)(2)(C)(ii), and 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act).

A food is adulterated under Section 402(a)(2)(C)(ii) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512 of the Act. On or about April 7, 2000, you sold a culled dairy cow back tag # 91FX1340 identified on USDA Case # 00-0026-WA Form # 373174 for slaughter as human food to [REDACTED]. USDA analysis of tissue samples collected from that animal identified the presence of gentamicin in the kidney at 1.0 parts per million (ppm). There is no allowable tolerance for gentamicin in the edible tissue of cattle.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions...whereby it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which are so inadequate that medicated animals bearing possibly harmful drug residues are likely to enter the food supply.

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For example, our investigator noted the following conditions on your farm:

1. You lack an adequate system for determining the medication status of animals you offer for slaughter.
2. You lack an adequate system for assuring that animals to which you administer medication have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drugs.
3. You lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in their labeling.
4. You lack an adequate system for assuring animals have been treated only with drugs which have been approved for use in their class of animal or species.

We request that you take prompt action to ensure that dairy cows and calves which you offer for sale as human food will not be adulterated with drugs or contain illegal residues.

Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act.

Causing the adulteration of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

You should be aware that it is not necessary for you to have personally shipped an adulterated animal into interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal to be slaughtered into food for human consumption where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

Our investigation revealed that the gentamicin residue came from your use of Garasol® (Gentamicin Sulfate Veterinary) on your dairy herd. Garasol® is approved for use on chickens and turkeys and is not approved for use on bovine animals. Your off label use of Garasol® is a deviation from Title 21, Code of Federal Regulations (21 CFR), Part 530, Extralabel Drug Use in Animals, which causes certain animal drugs used to medicate food producing animals, to be adulterated within the meaning of Section 501(a)(5) of the Act, in that they are new animal drugs which are unsafe within the meaning of Section 512(a)(4).

In October of 1994, Congress passed the Animal Medicinal Drug Use Clarification Act, which permits extra-label use under certain controlled conditions, specified in 21 CFR Part 530. Extra label use is only permitted if the use is by or on the lawful order of a licensed veterinarian within the context of a valid veterinarian/client/patient relationship and in conformance with criteria set forth in Part 530.

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Within fifteen (15) days of the receipt of this letter, notify this office in writing of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed.

Please send your reply to the Food and Drug Administration, Attention: Bruce Williamson, Compliance Officer, 22201 23rd Drive SE, Bothell, WA 98021. If you have questions regarding any issue in this letter, please contact Bruce Williamson, Compliance Officer, (425) 483-4976.

Sincerely,

A handwritten signature in black ink, appearing to read 'C. Breen', with a long horizontal flourish extending to the right.

Charles M. Breen
District Director

Enclosure:
Form FDA 483

cc: Dr. Ahmed/USDA/FSIS/Tissue Residue